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MV

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/388,221	09/01/99	REED J	P-LJ-3650

EXAMINER	
NIKODEM, D	
ART UNIT	**PAPER NUMBER**
1633	6

HM12/0310

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AIR MAIL

DATE MAILED: 03/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/388,221	REED, JOHN	
	Examiner	Art Unit	
	David Nikodem	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 Days FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☑ Other: Notice to comply with Seq. Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 11, 18, 27-29 and 38, drawn to NAC-associated nucleic acids, vectors, host cells, oligonucleotides and methods of expression, classifiable in class 536, subclasses 23.1 and 24.33 and class 435, subclasses 320.1, 325, 455 and 69.1.

II. Claims 12-17, 40, 41 and 52, drawn to NAC proteins, classifiable in class 530, subclass 350+.

III. Claims 19-22, 40-43, and 52-54, drawn to anti-NAC antibodies and methods using such, classifiable in class 530, subclass 387.1+ and in class 424, subclass 130.1+.

IV. Claims 10, 23 and 39, drawn to antisense-nucleic acids and compositions of such, classifiable in class 435, subclass 375 and class 536, subclass 24.5.

V. Claims 24-26, drawn to transgenic animals classifiable in class 800, subclass 274.

VI. Claim 30, drawn to a method of modulating the activity of an oncogenic protein using NAC, classifiable in class 435, subclasses 7.23 and 375.

VII. Claims 31-37, 40, 41, and 48-52, drawn to NAC/NAP associated methods, classified in class 435, subclasses 7.1 and 7.8.

VIII. Claims 42-44, drawn to methods of diagnosis using NAP, classified in class 435, subclass 7.8.

IX. Claims 45 and 47, drawn to a chimeric protein of NAC, classified in class 530, subclass 387.3.

X. Claim 46, drawn to a NAC protein with an LRR domain, classified in class 530, subclass 350+.

XI. Claim 55, drawn to an agent that binds a nucleotide binding site of NAC, unclassifiable because said agent was not identified in the claims.

XII. Claims 56-60, drawn to an agent that modulates NAC association with caspases, unclassifiable because said agent was not identified in the claims.

XIII. Claims 61-65, drawn to agent that modulates NAC association with CED-4, unclassifiable because said agent was not identified in the claims.

Note: Claims 42 and 43 are generic to groups III and VIII, and claims 40, 41 and 52 are generic to groups II, III and VII.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made using an alternative method from that claimed by Invention I, such as isolating NAC from cells that endogenously express NAC.

4. Inventions I and IV and V are patentably distinct, each from the other. Although the inventions are all drawn to nucleic acids, the scientific considerations and the materials and methods needed to perform the inventions are wholly different. Invention I is drawn to the nucleic acid sequence encoding NAC and uses of the sequence as a DNA probe and marker. It is necessary to develop specific hybridization protocols and to utilize materials and reagents unique to these techniques in order to practice the invention as claimed. Invention IV is drawn to antisense oligonucleotides and to the inhibition of NAC expression. It is necessary to design and develop anti-sense oligonucleotides that bind specifically to an accessible target sequence and inhibit expression of that target sequence. Furthermore, it is necessary to be able to determine whether or not a specific target is accessible to the oligonucleotide. Invention V is drawn to transgenic animals that express the specific NAC nucleic acid sequence.

It is necessary to develop vector constructs and delivery methods to properly express the nucleic acid sequence in an animal. Based on scientific considerations, divergent classification of the inventions, and different method steps, materials and reagents needed to practice the inventions as claimed, each invention is different from the other and would require independent and separate searches.

5. Inventions I, IV and V are patentably distinct from Inventions II, III, X and XI, each from the other. Although all inventions are based on NAC, Inventions I, IV and V are drawn to nucleic acids encoding NAC, Inventions II, X and XI are drawn to NAC proteins and Invention III is drawn to anti-NAC antibodies. Inventions I, IV and V are wholly different from Inventions II, III, X and XI, each from the other. Proteins, antibodies and nucleic acids are independent and patentably distinct products, each capable of supporting individual patents. Proteins can be used to identify ligands, while DNA can be used to make probes, while antibodies can be used in therapeutic procedures. The protocols and reagents required to practice the invention as claimed for the proteins, the antibodies and the nucleic acids are materially distinct and separate. The protein does not necessarily require the DNA or the antibody, the DNA does not necessarily require the protein or the antibody and the antibody does not necessarily require the protein or the DNA. Due to divergent classification and the aforementioned scientific considerations, the search for the inventions listed above would not be coextensive.

6. Inventions VI, VII, VIII, IX, XI, XII and XIII are patentably distinct, each from the other. Although all of the methods and/or agents of the claims of each invention are

related to NAC and the classifications may overlap, the inventions are distinct and independent because each invention is drawn towards different methods, each having different and unrelated steps and/or a different end result or goal. Invention VI is drawn to a method for modulating the activity of an oncogenic protein, whereas Invention VII is drawn to a method of identification of NAC/NAP association altering agents, whereas Invention VIII is drawn to a method of diagnosing a pathology, whereas Invention XII is drawn to caspases, whereas Invention XIII is drawn to CED-4. Furthermore, the development of different protocols and the use of different materials and reagents are needed to practice each invention as claimed. In view of the forgoing, the search among different inventions would not be coextensive.

7. The methods and agents in Inventions VI, VII, VIII, IX, XI, XII and XIII are independent and patentably distinct from the compositions in Inventions I-V, X and XI. Although the inventions may all be drawn to NAC and NAC related subject matter, the inventions are wholly different, each from each other. The differences in the methods, reagents and materials needed to practice the inventions as claimed are unrelated and vastly different because for each invention, the steps of the methods of the inventions need to be searched, not just the product of the methods. Furthermore, the scientific considerations necessary to determine the novelty of each invention are different, resulting in searches that are different and not coextensive.

8. Because Inventions I-XIII are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification

and recognized divergent subject matter and because inventions I-XIII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

JOHN L. LeGUYADER
PRIMARY EXAMINER
GROUP 1800

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March 8, 2000

Application No.: 09/388,221

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☒ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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